REMARKS

Telephone Interview

The Applicant thanks Examiner Miller for the helpful telephonic interview on April 8, 2008. During the interview, various potential claim amendments were discussed. Some of those potential claim amendments have been made herein.

Amendments

Independent claims 1, 49, and 50 have been amended to recite that the restrictive membrane is a single unitary sheet membrane, and that the restrictive member is coplanar with a plane of the anchor.

Claims 1, 49, and 50 have been further amended to recite the restrictive member being the sole restrictive element of the gastrointestinal implant device, a mechanical member that removably couples the anchor to the restrictive means after the anchor is placed in the stomach, and an outer perimeter edge of the restrictive membrane being coupled to the anchor.

103(a) Rejections

The Examiner has rejected Claims 1, 4, 10, 12, 13, 49, and 50 under 103(a) as being unpatentable over Kagan (US 2005/0240279).

Disclosed embodiments of Applicant's device will be discussed without limitation of the claims. As shown in Applicant's Figure 2, a restrictive device is implanted in the upper part of the stomach. The restrictive device is a two-piece device including an anchoring ring 226 and a removable restrictive member 224 with an aperture 218 through which food transits. The removable member can have an exterior perimeter 217 sized to contact the inner walls of the stomach. For example, the restrictive member has an external diameter between about 7 and about 20 centimeters. The restrictive member is planar in shape and is substantially planar and coplanar with a plane of the anchor. The restrictive member is a single-sheet unitary membrane, and is the sole restrictive member of the gastrointestinal implant device.

The width of the restrictive member (between about 7-20 cm to match the stomach size and depending on the size of the stomach pouch desired) allows it to sit in the stomach while

placing minimal tension on the stomach. Also, the planar shape of the membrane is advantageous in that one can obtain a small volume above the member with the device mounted to the stomach just below the GEJ.

The anchoring ring 226 is fixedly coupled to the stomach, and the restrictive membrane is removably coupled to the anchoring ring. The perimeter edge of the restrictive member is coupled to the anchor. As shown in Figures 3A and 3B, the restrictive membrane 224 can include a number of closed loops, or slots 240 arranged around the periphery. These slots 240 are configured for removably coupling to corresponding engagement hooks 230 around the periphery of the anchoring ring 226. After the anchoring ring 226 is anchored in the stomach, the restrictive membrane 224 is endoscopically delivered. The membrane is then attached to the anchoring ring 226.

Kagan describes an apparatus for treatment of morbid obesity. The Examiner refers separately to Kagan's embodiments of Figures 3 and 11. Kagan's Figure 3 shows an artificial stoma device 100 with a variable diameter stoma aperture 110. Kagan's Figure 11 shows a gastric sleeve device 200 with an artificial stoma device 100. The sleeve device includes a pyloric sleeve anchor 202 configured with openings 214 to allow secretions to pass though the pylorus in the small intestine.

The Examiner states that it would have been obvious to have the claimed width (7-20cm) since Kagan's device is in the upper stomach. She further states that Kagan discloses an implant comprising a substantially planar restrictive member (top planar stoma 100 in Fig. 3 or planar member 202 in Fig. 11) and the restrictive member being substantially planar with a plane of the anchor. Applicant respectfully disagrees with these points.

Firstly, in the embodiment of Figure 3, where Kagan's stoma and anchoring ring contact the walls of the stomach (see for example Kagan's Figure 1), the walls of the stomach are pulled to create a narrowing. The stoma device itself is not sized to sit in the stomach as is Applicant's planar restrictive member and anchor. As stated, the width of Applicant's planar restrictive member between about 7-20 cm matches the stomach size and allows it to sit in the stomach while placing minimal tension on the stomach, while Kagan's stoma device pulls on the stomach. Therefore, it would not be obvious to make Kagan's device 7-20cm, the actual diameter of the stomach, since Kagan's device is meant to pull on the stomach to narrow it and not fit within it.

Additionally, Kagan's stoma 100 is not a single unitary sheet, and a planar member that is coplanar with the anchoring ring, as is Applicant's member. It is an elongated, thick device that protrudes out of the anchoring ring.

Additionally, Applicant's restrictive member is the sole restrictive element of the gastrointestinal implant. Kagan's stoma 100 and gastric tube 200 (as shown in Fig. 11) are both restrictive elements. Thus, Kagan does not describe this limitation.

Finally, Kagan does not suggest a mechanical member that removably couples an outer perimeter edge of the restrictive member to the anchoring ring, after the anchor is placed in the stomach, as claimed by the Applicant (and as shown in Applicant's Figures 3A and 3B).

With regard to Kagan's Figure 11, Examiner refers to the pyloric sleeve anchor 202 as a restrictive member. The pyloric sleeve anchor preferably has openings to allow digestive secretions to pass through the pylorus (Kagan, Paragraph 183). This is not a restrictive member in the stomach, but an anchor with small holes in the pylorus that anchors the gastric sleeve. It is certainly not the sole restrictive member of the device, as the primary restriction is provided by the stoma 100 and sleeve 200. Further, the sleeve anchor 202 does not support the other claim elements described above, specifically the 7 to 20 centimeter size and removable coupling to an anchor with mechanical members.

Claims 1, 49, and 50 have been amended to recite that the restrictive member is coplanar with a plane of the anchor. Claims 1, 49, and 50 have also amended to recite the restrictive member being the sole restrictive element of the gastrointestinal implant device, a mechanical member that removably couples the anchor to the restrictive member after the anchor is placed in the stomach, and an outer perimeter edge of the restrictive member being coupled to the anchor. Kagan does not describe any of these limitations. Further, Kagan does not describe the outer width of the restrictive member being 7-20cm. These claims and any claims dependent on the same are therefore, allowable for at least these reasons.

Claims 1-10, 12-13, 17, 18, 49, and 50 have also been rejected over Khosravi (US 5,925,063). Khosravi describes a coiled sheet having a plurality of flaps mounted on its interior surface that project radially inward into a lumen formed by the interior surface of the apparatus when it is deployed (Khosravi, Abstract). The flaps can act as a filter, valve, or occlusive device. Khosravi discloses that the flaps are affixed to the sheet 21 along a marginal portion 29 using

any suitable means, including welding, brazing, or the use of a biocompatible adhesive (Khosravi, Col. 4, lines 36-40). Khosravi's device has teeth 24 that are engaged with openings 6 in edge 27. These teeth are for locking the device itself.

Firstly, Khosravi does not describe a restrictive member that is a unitary single sheet member as is recited in amended claims 1, 49, and 50. Khosravi's device is made up of a plurality of flaps, not a unitary single sheet. Further, Khosravi does not specifically describe the restrictive member being 7-20cm such that it fits the upper stomach as does the Applicant.

Further, Khosravi does not describe a mechanical member that removably couples the anchor to the restrictive member after the anchor is placed in the stomach, as is described by Applicant. Khosravi's flaps are attached to the sheet with an adhesive. and not a mechanical member. Further, his flaps are not attached to the sheet after the sheet has been positioned in the stomach. Thus, these limitations are not described by Khosravi.

Thus, Khosravi does not describe all of the limitations of independent claims 1, 49, and 50. Specifically, Khosravi does not describe the restrictive member being a single sheet unitary member, the member being 7-20 cm in diameter, and the anchor being removably coupled to the restrictive members with a mechanical member after the anchor is placed in the stomach. Therefore, independent claims 1, 49, and 50 or any claims dependent on these claims are allowable for at least these reasons.

Further, referring to Khosravi's Figures 2 and 6C, the Examiner states that Khosravi discloses an anchor having a plurality of clips 24 capable of penetrating tissue. Khosravi refers to teeth 24 that are engaged with openings 26 in edge 27. These are not spring clips configured to penetrate the muscular tissue of the stomach as is recited in Applicant's dependent claim 13 and independent claim 50. These are simply teeth that close the device itself. Therefore, dependent claim 13 and new claim 50 are also allowable over Khosravi for this reason.

Claims 1-10, 12-13, 17-18, 49 and 50 have also been rejected over Khosravi in view of Saadat.

Saadat describes a plurality of anchors adapted for intraluminal penetration into a wall of a gastro-intestinal lumen to prevent migration or dislodgement of the apparatus (Saadat, Abstract).

Khosravi does not describe all of the limitations of independent claims 1, 49, or 50 as previously stated. Saadat also does not describe any of the limitations of these claims that are missing in Khosravi. Thus, neither reference either alone or in combination describe all of the limitations of independent claims 1, 49, and 50, making these claims or any claim dependent on these claims allowable for at least this reason

Claims 1-13, 17-18, 20, 49, and 50 have also been rejected over Stack et al. (US 7,146,984).

As shown in Stack's embodiment in Figures 5A and 5B, Stack describes a pouch 40 to be implanted in the gastroesophageal region. The pouch 40 has an annular web 42 at its distal end, forming a distal orifice 44. A ring 46 is connected to the exterior of the webbing.

Referring to Figure 5B, the Examiner states that Stack discloses a substantially planar restrictive member (42a) that is planar with anchor 46a. Element 46a is not an anchor. Applicant assumes that the anchor is top ring (no reference numeral) on the proximal end of the pouch. Element 46a is a distal ring around the exterior of the webbing and is most probably for preventing the flimsy webbing material 42 from drooping. It is not for anchoring to the surrounding anatomy. The top ring is for anchoring to the gastroesophageal region. Therefore, the restrictive membrane 42 is not coplanar with a plane of the anchor, but is below the anchor.

The examiner states that Stack discloses the implant for placement in the stomach substantially as claimed, however does not disclose the size (width) of the restrictive member and of the aperture. The Examiner further states that it would have been obvious to have the width claimed (7-20 cm).

Applicant respectfully disagrees. Firstly, Stack's device is not placed in the stomach but in the gastroesophageal region. Thus, it is not obvious to make it of a size to fit the perimeter of the stomach.

Further, a device like Stack's would not function adequately in the stomach as does Applicant's device. In order to create an upper stomach chamber between 30-100 cc as is preferred by the Applicant, a device that itself had a significant length and resultant volume would need to be anchored high within the GEJ. Thus, Applicant's member being coplanar with the anchor allows it to be placed anywhere within the stomach to fully control the size of the

desired chamber, even to a small volume. Stack's pouch also has additional volume to consider when creating the stomach chamber.

Also, Stack does not describe a mechanical member that removably coupled the anchor to the restrictive members after the anchor is placed in the stomach. Stack nowhere indicated that the annular web 42 is removably attached to the ring 46 (which Examiner assumes to be the anchor) with a mechanical member after the ring 46 has been positioned in the stomach. As stated, Applicant assumes that Stack's top ring is the anchor of the device, and the annular ring is also not attached to the top ring with a mechanical member after the ring has been positioned in the stomach.

Further, because the top ring assumingly is the anchor, Stack does not describe an outer perimeter edge of the restrictive member 42 being coupled to the anchor, since it is below it at the bottom of the pouch.

Thus, Stack does not describe all of the limitations of amended claims 1, 49, and 50. Specifically, Stack does not describe the restrictive member having an outer width between 7 and 20 centimeters, the restrictive member being substantially planar and being coplanar with a plane of the anchor, a mechanical member that removably couples the anchor to the restrictive member after the anchor is placed in the stomach.

Further, with regard to claim 50, Stack also does not describe the limitation of spring clips attached to the anchor that penetrate tissue.

Therefore, claims 1, 49, and 50 or any claim dependent on these claims are allowable over Stack for at least these reasons.

Based on the preceding arguments, the Applicant requests that the Examiner withdraw all rejections of the claims.

Supplemental Information Disclosure Statement

A Supplemental Information Disclosure Statement (SIDS) is being filed concurrently herewith. Entry of the SIDS is respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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